

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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Center L. CAWSON  
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**Industry Exchange Workshop on Food and Drug Administration Clinical Trials Statutory and Regulatory Requirements**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

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**SUMMARY:** The Food and Drug Administration (FDA) Cincinnati District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

*Date and Time:* The public workshop will be held on Wednesday, December 7, 2005, from 8:15 a.m. to 5 p.m. and Thursday, December 8, 2005, from 8:15 a.m. to 4 p.m.

*Location:* The public workshop will be held at The Westin Cincinnati, 21 East 5th St., Cincinnati, OH 45202-3160, 513-621-7700, FAX: 513-852-5670.

*Contact:* Marie Falcone, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215-717-3703, FAX: 215-597-5798, e-mail: [mfalcone@ora.fda.gov](mailto:mfalcone@ora.fda.gov).

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of \$485

(member), \$560 (nonmember), or \$460 (government employee nonmember) (includes a 1-year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to [http://www.socra.org/FDA\\_Conference.htm](http://www.socra.org/FDA_Conference.htm). (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–345–7749, or FAX: 215–345–7369, or e-mail: [socramail@aol.com](mailto:socramail@aol.com). Attendees are responsible for their own accommodations. To make reservations at The Westin Cincinnati at the reduced conference rate, contact The Westin Cincinnati see *Location*) through November 7, 2005, or until the SoCRA room block is full.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

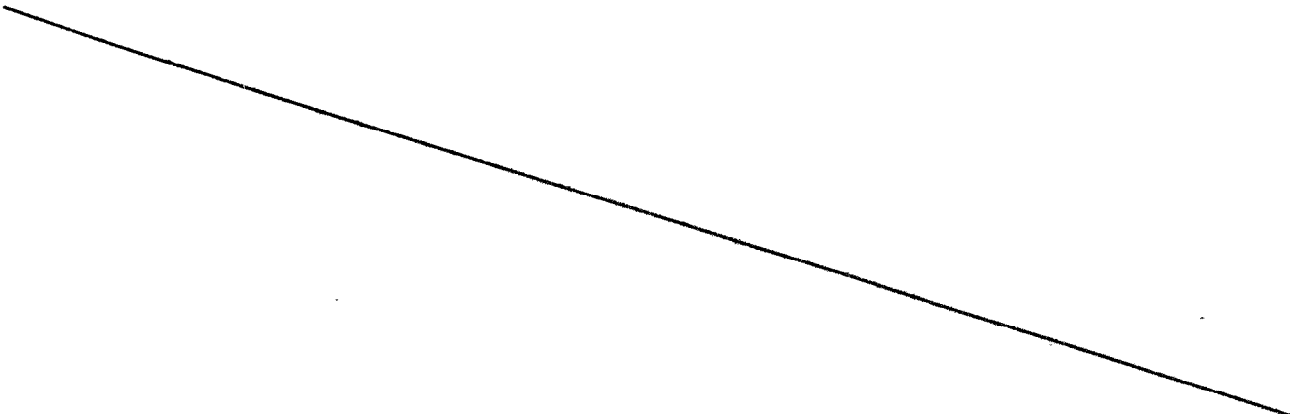
If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The “FDA Clinical Trials Statutory and Regulatory Requirements” workshop helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health by educating researchers on proper conduct of clinical trials. FDA has made

education of the research community a high priority to assure the quality of clinical data and protect research subjects.

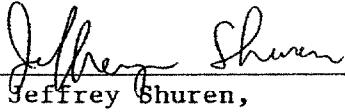
The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- FDA and confidence in the conduct of clinical research;
  - Medical device, drug, and biological product aspects of clinical research;
  - Investigator initiated research;
  - Pre-investigational new drug application (IND) meetings and FDA meeting process;
  - Informed consent requirements;
  - Ethics in subject enrollment;
  - FDA regulation of Institutional Review Boards;
  - Electronic records requirements;
  - Adverse event reporting;
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- How FDA conducts bioresearch inspections; and
- What happens after the FDA inspection.

Dated: **SEP 12 2005**  
September 12, 2005.

  
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Jeffrey Shuren,

Assistant Commissioner for Policy.

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